Automatic Patient Control Device

Field of the Invention

The present invention relates to an automatic patient control device that delivers a medium to a patient.

Background of the Invention

Gaymar Industries, Inc. (the assignee of the present invention) is the owner and manufacturer of the MEDI-THERM II® hypo/hyperthermia machine. This machine delivers water to a blanket (*i.e.*, Gaymar's Hypo/hyper thermia blanket, Gaymar's THERMACARE® blanket or Gaymar's MEDI-TEMP® blanket), a mattress pad (*i.e.*, Gaymar's Alternating Pressure Pad (model no. EFF302)), a chair pad, or a mattress unit (*i.e.*, Gaymar's CLINIDYNE® mattress)(collectively the blankets, pads, and mattresses and obvious variations thereof are hereinafter "Objects"). In particular, the Objects surround a patient or applied to predetermined portions of the patient.

INS A1 ~~The object of the MEDI-THERM II® hypo/hyperthermia machine is to stabilize a patient who is experiencing hypothermia or hyperthermia or, in some instances, to actively cause hypothermia or hypothermia as therapy. To understand the MEDI-THERM II® device, we will revert to Figure 1 (prior art) which is a flow diagram of how the MEDI-THERM II® device distributes water to and from an Object. The liquid medium enters MEDI-THERM II® device through return inlet 52. From return inlet 52, the liquid medium traverses through a first conduit 30 to a first solenoid valve 32 for cold liquid medium or a second solenoid valve 34 for warm liquid medium.~~

From the first solenoid valve 32, the liquid medium goes through a second conduit 36 and a first cold inlet 37 to a cold reservoir 38. The cold reservoir 38 is a conventional cooling unit that cools the water, *i.e.*, a refrigeration system's or air conditioner's evaporator. The evaporator in the reservoir maintains a large quality of water at a predetermined temperature - normally $4^{\circ}C$ - (hereinafter "Cold Water"). Water entering the reservoir is cooled by mixing with the Cold Water already in the reservoir (hereinafter "Reservoir Water".) If the cold reservoir 38 overflows, the Cold Water escapes from the device 10 through an overflow outlet 40. The Cold Water then flows through a cold outlet 41 of the cold reservoir 38 and a third conduit 42 to a manifold 44.

Similarly from the second solenoid 34, the water goes to a hot reservoir 46 through a fourth conduit 48 and a hot inlet port 49. The hot reservoir 46 is a conventional heating apparatus that heats the liquid medium (hereinafter "Warm Water"). The Warm Water flows through the warm outlet 56 to the manifold 44.

At the manifold 44 the Warm Water and the Cold Water converge. The selection of which return water path is active and its length of time active is controlled via solenoid valves 32 and 34 to attain a desired temperature (hereinafter "Mixed Water"). The Mixed Water is drawn through a sixth conduit 74 by a conventional pump 76, to supply outlet 14. A flow switch 78 on the sixth conduit 74 senses whether the Mixed Water reaches the supply outlet 14. Obviously, when the flow switch 78 is on, the Mixed Water reaches the supply outlet 14. And when the flow switch 78 is off, the Mixed Water fails to reach the supply outlet

14. A seventh conduit 80 connects with the first conduit 30 to provide quelling of temperature overshoot when no Object is connected.

When the Mixed Water reaches the supply outlet 14, the Mixed Water is released into the outlet conduit 18 into the Object 16. The Mixed Water traverses through the Object 16 to the return conduit 50 and into the return inlet 52.

The Mixed Water temperature is altered with the first solenoid valve 32 which controls the Warm Water and the second solenoid valve 34 which controls the Cold Water. The amount of water each valve 32, 34 allows into the manifold 44 depends on the temperature of the mammal 20 and the temperature of the Mixed Water in the Object.

The temperature of the mammal 20 is measured by a first conventional temperature sensing device (i.e. thermistors or thermocouples) 130 connected to a preselected portion of the mammal 20 and interconnected to a processing unit 90. The measurement from the first temperature sensing device 130 is transmitted to a processing unit 90.

The temperature of the Mixed Water in the Object is measured by a second conventional temperature measuring device 132 placed in the Object 16, in the supply conduit 18, the supply outlet 14, the sixth conduit 74, or manifold 44. The measurement from the second temperature measuring device 132 is transmitted to the processing unit 90.

The processing unit 90 compares the measurement from the first temperature sensing device 130 (hereinafter "First Measurement") to the Set Point Body temperature of the mammal 20 (hereinafter "Set Point

Body Temperature"). The processing unit 90 determines whether First Measurement is above or below the Set Point Body Temperature.

Initially when the First Measurement is above the Set Point Body Temperature, the MEDI-THERM II® device, by design, applies the coldest water available (normally 4°C) to the Object 16. Figure 2 (prior art) illustrates this design feature in section 200 wherein the temperature of the First Measurement is represented as line 201, the Set Point Body Temperature is represented as line 202, and the Mixed Water is represented as line 203. Once the First Measurement 201 falls below the Set Point Body Temperature 203, the processing unit uses the solenoid valves 32, 34 to alter the temperature of the Mixed Water, not at a predetermined differential from the First Measurement, to eventually stabilize the patient to the Set Point Body Temperature. See section 204 of Figure 2.

Likewise, when the First Measurement is below the Set Point Body Temperature, the MEDI-THERM II® device, by design, applies the warmest water available (normally 42°C) to the Object 16. Once the First Measurement 201 falls above the Set Point Body Temperature 203, the processing unit uses the solenoid valves 32, 34 to alter the temperature of the Mixed Water, not at a predetermined differential from the First Measurement, to eventually stabilize the patient to the Set Point Body Temperature. See section 204 of Figure 2.

The MEDI-THERM II® device, however, can sometimes cause discomfort to the patient. This discomfort can occur when the MEDI-THERM II® device applies the coldest water available (normally 4°C) or the warmest water available (normally 42°C) into the Object during the

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initial time frame, shown in section 200 of Figure 2, or when the First Measurement and the Set Point Body Temperature difference is not-so-great but exists for a long time. When the patient is exposed to the coldest or warmest water available, the patient may experience some discomfort.

The present invention solves this problem.

Brief Description of the Drawings

Figure 1 illustrates a prior art schematic flow diagram of how the MEDI-THERM II® hypo/hyperthermia machine distributes water to and from an Object.

Figure 2 illustrates a prior art graph of the Figure 1.

Figure 3 illustrates the exterior embodiment of the present invention.

Figure 4 illustrates a schematic flow diagram of how the present invention distributes a liquid medium to and from an Object

Figures 5A, 5B, and 5C illustrate graphs showing the actual temperature of a patient and the temperature of the desired medium applied to the patient over time of the present invention.

Figure 6 illustrates an alternative embodiment of Figure 4.

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Summary of the Present Invention

The present invention relates to regulating the temperature of a desired medium that is applied to the exterior surface of a mammal. These devices have been used in the past but not with the ability to control the temperature of the desired medium in a predetermined ratio to the temperature of the mammal. With such

control, the present invention decreases the chance of discomforting the patient when the patient's temperature is being brought to a Set Point Body temperature.

Detailed Description of the Present Invention

Ins A3 ~~One embodiment of the present invention is illustrated in Figure 3. This embodiment relates to a liquid medium delivery device 10. The exterior of the device 10 has at least one supply outlet 14, a kill switch 444 which can shut down the entire device 10 by conventional interconnections between the various components of device 10, a display/input unit 46, at least one outlet conduit 18, a return conduit 50, a return inlet 52, and an Object 16.~~

Figure 4 is a flow diagram of how device 10 distributes the liquid medium. The liquid medium enters device 10 through the return inlet 52. From return inlet 52, the liquid medium traverses through the first conduit 30 to the first solenoid valve 32 for a cold liquid medium or the second solenoid valve 34 for a warm liquid medium.

From the first solenoid 32 which is controlled by a processor unit 90 (to be described later), the liquid medium goes through a second conduit 36 and the first cold inlet 37 of the cold reservoir 38 to the cold reservoir 38. The cold reservoir 38 is a conventional cooling unit that cools a liquid, *i.e.*, a refrigeration system's evaporation or an air conditioner's evaporator. The evaporator in the reservoir maintains a large quantity of fluid at a predetermined temperature normally 4°C (hereinafter "Cold Medium"). Liquid medium entering the reservoir is cooled by mixing with the liquid medium already within the reservoir. If the cold

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reservoir 38 overflows, the liquid medium escapes from the device 10 through the overflow outlet 40. The Cold Medium then flows through the cold outlet 41 of the cold reservoir 38 and the third conduit 42 to a manifold 44.

Similarly from the second solenoid 34 which is controlled by the processor unit 90, the liquid medium goes to a hot reservoir 46 through the fourth conduit 48 and the hot inlet port 49 of the hot reservoir 46. The hot reservoir 46 is a conventional heating apparatus that heats the liquid medium (hereinafter "Warm Medium"). The warm Medium flows through the warm outlet 56 of the hot reservoir 46 to the manifold 44.

At the manifold 44, the Warm Medium and the Cold Medium converge. The selection of which liquid medium path is active and its length of time active is controlled via solenoid valves 32 and 34 to attain a desired temperature. The Mixed Medium is drawn through the sixth conduit 74 by the conventional pump 76, to supply outlet 14. A flow switch 78 on the sixth conduit 74 senses whether the Mixed Medium reaches the supply outlet 14. Obviously, when the flow switch 78 is on, the Mixed Medium reaches the supply outlet 14. And when the flow switch 78 is off, the Mixed Medium fails to reach the supply outlet 14. A seventh conduit 80 connects with the first conduit 30, to provide quelling of temperature overshoot when no Object is connected.

When the Mixed Medium reaches the supply outlet 14, the liquid medium is released into the outlet conduit 18 into the Object 16. The Mixed Medium traverses through the Object 16 to the return conduit 50 and into the return inlet 52. And the process is repeated.

The Mixed Medium temperature is altered by the first solenoid valve 32 which controls the intake of the

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Warm Medium and the second solenoid valve 34 which controls the intake of the Cold Medium. The amount of medium each solenoid valve 32, 34 allows into the manifold 44 depends on the temperature of the mammal 20 and, sometimes depending on the embodiment of the present invention, the temperature of the Mixed Medium in the Object.

The temperature of the mammal 20 is measured by the first conventional temperature sensing device 130 connected to the preselected portion of the mammal 20 and interconnected to the processing unit 90. The measurement from the first temperature sensing device 130 is transmitted to the processing unit 90.

The temperature of the Mixed medium in the Object is measured by the second conventional temperature measuring device 132 placed in the Object, in the supply conduit 18, the supply outlet 14, the manifold 44, or the sixth conduit 74. The measurement from the second temperature measuring device 132 is transmitted to the processing unit 90.

Initially, the processing unit 90 compares the measurement from the first temperature sensing device 130 (hereinafter "First Measurement") to the Set Point Body temperature of the mammal 20 (hereinafter "Set Point Body Temperature"). The processing unit 90 determines the differential and, in return, adjusts the temperature of the Mixed Medium to a preset differential by controlling the solenoid valves 32, 34.

When the First Measurement is above the Set Point Body Temperature, the processing unit 90 controls the first and second solenoid valves 32, 34 to alter the temperature of the Mixed Medium to a predetermined differential from the First Measurement. The

predetermined differential ranges from 0.1 to 35 degrees Celsius, and preferably ranges from 5 to 15 degrees Celsius, below the First Measurement.

Initially when the First Measurement is above the Set Point Body Temperature, the device 10 applies, by the processing unit 90 controlling the first and second solenoids 32, 34, a Mixed Medium into the Object 16 having a predetermined differential from the First Measurement. The predetermined differential ranges from 0.1 to 35 degrees Celsius, and preferably ranges from 5 to 15 degrees Celsius, below the First Measurement. Figures 5a (a 10°C differential) and 5b (a 15°C differential) illustrate this design feature in section 400 wherein the temperature of the First Measurement is represented as line 401, the Set Point Body Measurement is represented as line 402, and the Mixed Medium is represented as line 403 at different differentials. Once the First Measurement 401 falls below the Set Point Body Temperature 402, the first and second solenoid valves 32, 34 alter the temperature of the Mixed Medium, to eventually stabilize the patient to the Set Point Body Temperature. See section 404 of Figures 5A and B.

Likewise, when the First Measurement is initially below the Set Point Body Temperature, the processing unit 90 controls the first and second solenoid valves 32, 34 to alter the temperature of the Mixed Medium to a pre-set differential from the First Measurement. The pre-set differential ranges from 0.1 to 35 degrees Celsius, and preferably ranges from 5 to 15 degrees Celsius, above the actual temperature, so long as the processing unit 90 does not alter the temperature of the Mixed Medium above a predetermined-maximum temperature. The predetermined-maximum temperature is 0.1 to 10

degrees Celsius, and preferably about 5 degrees Celsius, above the normal temperature of the mammal.

And when the First Measurement is about the Set Point Body Temperature, the processing unit 90 controls the first and second valves 32, 34 to alter the temperature of the Mixed Medium to a temperature which will maintain the First Measurement about the Set Point Body temperature.

The liquid medium can be any liquid that transfers thermal energy to a mammal 20 and wherein the liquid can be readily altered to a Warm Medium or a Cold Medium, like water or water-based solutions.

Alternatively, the liquid medium set forth in the present invention can be substituted by a gaseous medium, like air. When device 10 delivers air instead of a liquid medium, device 10 is altered. Instead of having valves 32, 34, conduits 48, 36, 42, and reservoirs 38, 46, the device 10 has a different temperature and intake system.

Turning to Figure 6, the air is drawn into device 10 through the inlet 52 by a conventional fan 540. From the inlet 52, the air medium traverses through a ninth conduit 302 to a plenum 304. The plenum 304 has a cooling unit 306, like an air conditioner, and a heating unit 308, like a heat pump. The processing unit 90 controls the cooling unit 306 and the heating unit 308 by conventional methods well known to those skilled in the art.

The air then escapes into the manifold 44 and follows route set forth for Figure 3, except the air does not return to the device 10 from the Object 16. The temperature of the Mixed Medium in the Object 16 is measured by the second conventional temperature

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measuring device 132 placed in the Object 16, in the supply conduit 18, the supply outlet 14, the sixth conduit 74, the manifold 44 or the plenum 304. The measurement from the second temperature measuring device is transmitted to the processing unit 90.

The processing unit 90, in return, alters the operation of the cooling unit 306 and the heating unit 308 to obtain the desired air temperature.

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In one embodiment of the present invention, the values for the predetermined differential, the pre-set differential, the predetermined-maximum temperature, the Set Point Body Temperature, and the pre-selected differential can be entered into the processing unit 90 through the display/input unit 46 by a user. Alternatively, these values can be pre-programmed and activated by merely striking a desired switch. Device 10 when using these values decrease the discomfortness to the patient 20.

Alternatively, the processing unit 90 can be programmed and/or pre-set to alter the temperature of the Mixed Medium and/or the temperature of the mammal 20 at a set rate. For example, altering the temperature of the Mixed Medium or mammal 16 at 2°C, or any other temperature change, per hour. These changes can occur in time increments, as well. For example, the processing unit 90 can be programmed, as illustrated in Figure 5c wherein the lines 401 and 403 are defined above, to (1) cool the mammal 16 (or Mixed Medium) to 34°C at 2°C/hour during a first time period (area 600), (2) cool the mammal 16 (or Mixed Medium) to 32°C using a 20°C maximum differential during a second time period (area 601), (3) during a third time frame, the mammal's (or Mixed Medium's) temperature is to be maintained at

32°C - to maintain this temperature for the mammal the Mixed Medium is at a maximum pre-set differential, *i.e.*, a 10°C maximum differential from the mammal's temperature - for 1 hour (area 602); and (4) raise the mammals' (or Mixed Medium's) temperature to 37°C, or any other predetermined temperature at a rate of 4°C per hour (area 603). Obviously, these examples can be used with different temperatures, different differentials, and different, desired rates. By controlling these rates, temperatures, and differentials individually and/or collectively, by manual means of inputting the data into the processing unit 90, automatic means of a pre-programmed rate and/or temperature, or a combination of both means, the processing unit 90 controls the solenoid valves 32,34, 320 and manifold 44 to distribute the Mixed Medium at the predetermined temperature and/or predetermined rate.

While preferred embodiments of the present invention have been disclosed, it will be appreciated that it is not limited thereto but may be otherwise embodied with the scope of the following claims.

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